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<b>Notice of Allowability</b>	<b>Applicati n N .</b>	<b>Applicant(s)</b>	
	10/627,484	KOCHAT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Taylor Victor Oh	1625	

**-- The MAILING DATE of this communicati n appears on the cover sh et with the corresp ndence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/28/04.
2. ☒ The allowed claim(s) is/are 1 and 3-6, renumbered as claims 1-5.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachm nt(s)**

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|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>1/6/05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                       |
|   | 9. <input type="checkbox"/> Other _____.   |

Examiner's Amendment and Reasons of Allowance

The Status of Claims

Claims 1 and 3-6 are pending.

Claims 1 and 3-6 have been allowed.

Claims 2 and 7 have been canceled.

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with an attorney of record, Mr. Alan Nadel (Reg# 27363) on 1/6/05 .

I. The application has been amended as follows:

In claim 1, line 1 on page 12 (amendment dated on 10/28/04):

The term “ -- substantially --” before the word “ enantiomerically” has been replaced with “ greater than 99 % ”.

In claim 1, line 9 on page 12 (amendment dated on 10/28/04):

The term “ -- protected --” has been inserted before the word “ (2S)-pyroglutamic acid”.

In claim 1, lines 10-11 on page 12 (amendment dated on 10/28/04):

The phrase “ -- converting the starting material to a 4-enamine pyroglutamic acid intermediate or ester thereof--” has been replaced with “reacting the starting material with an amide or an acetal at a temperature ranging from 70<sup>0</sup> C to 130<sup>0</sup>

C to form a protected 4-enamine pyroglutamic acid intermediate or ester thereof ”.

In claim 1 , line 12 on page 12 (amendment dated on 10/28/04):

The term “ -- protected --” has been added before the word “ 4-enamine intermediate ”; the term “ --form-- ” has been added after the word “ to” ; and also the term “ -- protected --” has been added before the word “ 4-hydroxymethylidene pyroglutamic acid intermediate ”; the term “--and-- “ has been deleted after the symbol “ ; ” .

In claim 1 , lines 14-15 on page 12 (amendment dated on 10/28/04):

The phrase “ -- reducing the 4-hydroxymethylidned intermediate to a 4-methylene pyroglutamic acid or an ester thereof --” has been replaced with “reducing in a basic solution the protected 4-hydroxymethylidned intermediate to form a protected 4-methylene pyroglutamic acid or an ester thereof ”; the term “--and-- “ has been added after the symbol “ ; ” .

In claim 1 , lines 16-17 on page 12 (amendment dated on 10/28/04):

The term “ -- protected --” has been added before the word “ 4-methylene pyroglutamic acid ”; and the phrase “--esters and salts--“ before the word “ thereof” has been replace with “ an ester or salt” .

In claim 3 , line 22 on page 12 (amendment dated on 10/28/04):

the phrase “ -- 70<sup>0</sup> C to 130<sup>0</sup> C --“ has been replaced with “ 105<sup>0</sup> C to 115<sup>0</sup> C ”.

In claim 4 , line 1 on page 13 (amendment dated on 10/28/04):

The term “ -- protected --” has been added before the word “ 4-enamine intermediate ”.

In claim 5 , line 1 on page 13 (amendment dated on 10/28/04):

The term “ -- protected --” has been added before the word “ 4-hydroxymethylidene intermediate ”.

Claims 2 and 7 have been canceled.

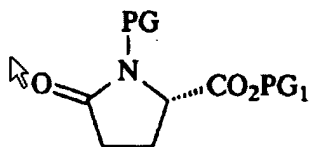
II. The following is an examiner's statement of reasons for allowance:

- The close reference for the current invention is Ezquerra et al(Tetrahedron: Asymmetry (1994), 5(5), p. 921-6).

Ezquerra et al discloses the process of preparing 4-methylene-L-glutamic acid in the following steps:

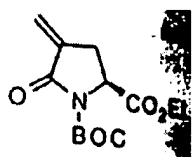
- a. reacting a solution of  $(\text{Me}_3\text{Si})_2\text{NH}$  in dry THF and a solution of ethyl N-Boc-pyroglutamate at  $-78^\circ\text{C}$  and allowing the reaction mixture at room temperature, and further hydrolyzing the resultant solution with water;
- b. reducing ethyl-1-(tert-butoxycarbonyl)-4-(dimethylaminomethyl)pyroglutamate in the presence of  $\text{NaHCO}_3$  at room temperature;
- c. hydrolyzing ethyl-1-(tert-butoxycarbonyl)-4-(methylene)pyroglutamate in the presence of lithium hydroxide in THF followed by treatment of  $\text{HCl}$  in ETOAC at room temperature.

The instant invention, however, differs from the prior art in that the claimed starting



compound is

,whereas the prior art starting compound is



; in the prior art, there is no reaction between the starting compound and the amide or the acetal at a temperature of from 70<sup>0</sup> C to 130<sup>0</sup> C. Therefore, the claimed process and the prior art process are completely different from each other. In addition, unless all limitations of the claims are met, there is no prior art rejection. See In re Zurko 59 USPQ 2d 1690 (Fed Cir. 1991) and In re Lee, 61 USPQ 1430 (Fed Cir. 1991).

Therefore, the claimed invention would not have been obvious to the person with an ordinary skill in the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning the communication after allowance such as sending all post-allowance correspondence should be directed to "Box Issue Fee" or faxed directly to PUBS at 703-305-8755. This will expedite the process of these papers.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*My V. Jh*  
*1/6/05*

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